

**In the United States Court of Federal Claims**  
**OFFICE OF SPECIAL MASTERS**  
**No. 17-325V**  
**Filed: December 28, 2020**

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SHARON LABOUNTY,	*	
	*	
Petitioner,	*	TO BE PUBLISHED
	*	
v.	*	
	*	Special Master Katherine E. Oler
	*	
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES,	*	
	*	Chronic Regional Pain Syndrome
Respondent.	*	(CRPS); Flu Vaccine; Needle Stick
	*	
*****	*	

*Howard Gold*, Gold Law Firm, LLC, Wellesley Hills, MA for Petitioner  
*Christine Becer*, U.S. Department of Justice, Washington, DC, for Respondent

**RULING ON ENTITLEMENT<sup>1</sup>**

On March 9, 2017, Sharon LaBounty (“Ms. LaBounty” or “Petitioner”) filed a petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10.<sup>2</sup> (“Vaccine Act” or “the Program”) alleging that the flu vaccination she received on September 18, 2015 caused her to suffer a reaction which was diagnosed as brachial plexopathy and brachial neuritis. Petition at 1, ECF No. 1. Petitioner filed an amended petition (“Amended Pet. 1”) on August 15, 2018 alleging her flu vaccination caused her to develop a shoulder injury related to vaccine administration (“SIRVA”). Amended Pet. 1 at 1, ECF No. 23. On September 15, 2018, Petitioner filed a second amended petition (“Amended Pet. 2”) alleging that the flu vaccination caused her to develop Chronic Regional Pain Syndrome (“CRPS”). Amended Pet. 2 at 1, ECF No. 24.

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<sup>1</sup> This Ruling will be posted on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Ruling will be available to anyone with access to the internet.** As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Ruling’s inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, this Ruling will be available to the public in its present form. *Id.*

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Upon review of the evidence submitted in this case, I find that Petitioner has met her burden in showing that the flu vaccination she received on September 18, 2015 caused her to develop CRPS. She is therefore entitled to compensation under the Vaccine Act.

### **I. Procedural History**

Petitioner filed her petition on March 9, 2017; she alleged the flu vaccination she received on September 18, 2015 caused her to suffer from brachial plexopathy and brachial neuritis.<sup>3</sup> Pet. at 1, ECF No. 1. On October 1, 2017, Respondent filed a Rule 4(c) Report stating that compensation should be denied and the case should be dismissed. Resp't's Rep. at 1, ECF No. 11. After multiple extensions of time, Petitioner filed a status report on July 31, 2018 indicating she was "unable to offer an expert report in support of causation for the diagnosis of brachial plexus," and requested additional time to confer with her counsel on how she wished to proceed. Status Rep. on 7/31/18, ECF No. 21.

On August 13, 2018, Petitioner filed a status report stating that her Petition alleging the flu vaccination caused her to develop brachial plexus was based on her treating physician's initial diagnosis, however, "[h]e is unable to provide an expert report in support of this diagnosis." Status Rep. on 8/13/2018, ECF No. 22. Petitioner stated her medical records are consistent with a SIRVA injury and requested time to file an amended petition and an expert report. *See id.*

Petitioner filed an amended petition on August 20, 2018 alleging the flu vaccine caused her to suffer from "a table-injury, SIRVA". Amended Pet. 1 at 1, ECF No. 23. On September 15, 2018, Petitioner filed another amended petition alleging the flu vaccine caused her to suffer from CRPS. Amended Pet. 2 at 1, ECF No. 24. Petitioner filed an expert report written by Dr. Marcel Kinsbourne on the same day. Ex. 11, ECF No. 25.

On November 16, 2018, I held a status conference with the parties. *See* Minute Entry on 11/19/2018; Scheduling Order on 11/19/2018, ECF No. 28. I informed the parties that Dr. Kinsbourne did not utilize the Budapest Criteria in diagnosing Ms. LaBounty with CRPS and that I understood the Budapest Criteria to be the current diagnostic standard. *See* Scheduling Order on 11/19/2018. I ordered both parties to file expert reports addressing the applicability of the Budapest Criteria in the context of Petitioner's symptoms. *See id.*

On December 17, 2018, Respondent filed an expert report from Brian Callaghan, M.D., M.S. Ex. A, ECF No. 29. In this report, Dr. Callaghan stated Petitioner had many pre-existing conditions and the symptoms, which dated back to 2008 and that she experienced shortly after the September 18, 2015 flu vaccination were more likely to be a "central sensitization syndrome." Ex. A at 2.

On January 15, 2019, Petitioner submitted a supplemental affidavit. Ex. 13, ECF No. 30. On January 16, 2019, Petitioner submitted a supplemental expert report from Dr. Marcel

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<sup>3</sup> This case was initially assigned to Special Master Roth (ECF No. 4) and re-assigned to my docket on June 8, 2018 (ECF No. 19).

Kinsbourne. Ex. 14, ECF No. 31. On April 29, 2019, Respondent filed a supplemental expert report from Dr. Callaghan. Ex. C, ECF No. 33.

On August 6, 2019, I held a status conference with the parties. *See* Minute Entry on 8/7/2019; Scheduling Order on 8/7/2019, ECF No. 34. Both parties agreed to a ruling on the record after it was confirmed that all evidentiary materials were submitted. Scheduling Order on 8/7/2019, ECF No. 34. On September 6, 2019, the parties filed a joint status report stating they had no additional evidentiary materials to submit. Status Rep. on 9/6/2019, ECF No. 35.

On October 18, 2019, Petitioner filed a Motion for a Ruling on the Record. Pet'r's Mot. on 10/18/2019, ECF No. 37. On the same day, Petitioner also filed additional medical literature. Ex. 15a-f, ECF No. 38. On December 17, 2019, Respondent filed a Response to Petitioner's Motion for a Ruling on the Record. ECF No. 40. Petitioner filed a Reply brief on December 21, 2019. ECF No. 41.

On January 10, 2020, I held a status conference with the parties. *See* Minute Entry on 1/10/2020; Scheduling Order on 1/10/2020, ECF No. 42. I informed the parties that I had additional questions for their experts with regards to CRPS and whether Petitioner met the Budapest Criteria for a CRPS diagnosis. Scheduling Order on 1/10/2020, ECF No. 42. Petitioner filed an expert report from Dr. Kinsbourne on March 29, 2020. Ex. 16, ECF No. 44. Respondent filed an expert report from Dr. Callaghan on March 31, 2020. Ex. D, ECF No. 45.

I held another status conference on April 6, 2020 with the parties to discuss the parties' recent filings. *See* Minute Entry on 4/6/2020; Scheduling Order on 4/6/2020, ECF No. 46. Dr. Kinsbourne repeatedly referred to the IASP criteria but did not answer my questions concerning Petitioner's diagnosis based on the Budapest criteria, furthermore, inconsistencies with the font and of the absence of a response to my third question caused me to question whether the report was complete. *See* Scheduling Order on 4/6/2020, ECF No. 46. I ordered Petitioner to file a status report on the completeness of Dr. Kinsbourne's report. I also ordered Respondent to file a status report regarding Dr. Callaghan's position as to whether the Budapest criteria were the prevailing criteria for a CRPS diagnosis. *See id.*

On April 7, 2020, Respondent filed a status report stating Dr. Callaghan concurred that the Budapest Criteria were "the most accepted diagnostic criteria for the diagnosis of CRPS." Resp't's Status Rep., ECF No. 47. On April 25, 2020, Petitioner filed a supplemental report from Dr. Kinsbourne. Ex. 17 at 2, ECF No. 48.

On May 24, 2020, the parties filed a joint status report indicating the record was complete for a ruling on the record. Pet'r's Status Rep., ECF No. 50.

## **II. Medical Records**

### **A. Petitioner's Health Prior to the Allegedly Causal Vaccination**

Petitioner had a history of prediabetes, allergies, gastroesophageal reflux disease (“GERD”), hiatal hernia, thyroid cancer, deep vein thromboses (“DVT”), irritable bowel syndrome with constipation, anxiety, migraines, hypothyroidism, and appendicitis. Ex. 4<sup>4</sup> at 46; Ex. 7 at 4.

Petitioner saw Dr. Ingrid Fuller on March 26, 2014 for a medication follow-up. Ex. 4 at 92. During this appointment, Petitioner complained of cold and numb feet, migraines, fibroid pain, and pain in her hands, wrists, and lower back. *Id.* Dr. Fuller noted Petitioner had joint pain but stated it was unclear whether it was osteoarthritis or an autoimmune problem but referred Petitioner to a rheumatologist to examine possible Raynaud’s phenomenon. *Id.*

On April 18, 2014, Petitioner saw Dr. Raymond Pertusi, a rheumatologist. Ex. 4 at 80. Dr. Pertusi noted that since 2008 Petitioner has experienced pain and an aching sensation located in her ankles, knees, hands, neck, lower back, and hips. *Id.* Dr. Pertusi also noted that Petitioner has “1-3 fingers turn white on cold exposure” and she experienced fatigue, cramping, and numbness in her fingers and toes. *Id.* Dr. Pertusi’s impression was that Petitioner’s “pain generator is likely a central sensitization syndrome that could be related to remote trauma (Abuse x 3) and likely PTSD.” *Id.* at 82.

On June 4, 2015, Petitioner visited an emergency room for chest pain and followed-up with Dr. Fuller on June 9, 2015. Ex. 4 at 63. Petitioner also informed Dr. Fuller she was having cramping in her legs, especially in her left leg, and was concerned of a blood clot or deep vein thrombosis. *Id.* Petitioner obtained a CAT scan, which was negative for any pulmonary embolisms. *Id.*

On July 27, 2015, Petitioner saw Dr. Susan Shih for five years of joint pain in her mid-lower back, hips, ankles, wrists, and “pain in her right hand associated with swelling in the right fourth and fifth PIP (“proximal interphalangeal”) joints.” Ex. 4 at 55.

Petitioner received a flu vaccination in her left deltoid at a CVS Pharmacy on September 18, 2015. Ex. 3.

### **B. Petitioner’s Health after the Allegedly Causal Vaccination**

On September 29, 2015, Petitioner saw her primary care physician (“PCP”), Dr. Ingrid Fuller for pain she experienced in her upper left arm “fifteen minutes after she received the flu injection.” Ex. 4 at 44. Dr. Fuller noted that it was Ms. LaBounty’s first flu shot and Petitioner had trouble lifting her left arm because of the pain, but there was no swelling. *Id.* The pain in her left arm began improving after a week and her right arm began to hurt. *See id.* Petitioner did not have a fever but felt feverish. Petitioner had seen a rheumatologist for finger and wrist joint swelling but the finger swelling appeared before she received the flu vaccine. *See id.*

On September 30, 2015, Petitioner visited Dr. Susan Shih a rheumatologist, for an “urgent evaluation”. Ex. 4 at 43. Dr. Shih noted that Petitioner received a flu shot on September 18, 2015 and

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<sup>4</sup> Exhibit 4 and Exhibit 9 are identical. Therefore, only Exhibit 4 will be cited for the sake of clarity.

almost immediately developed severe pain in the left upper arm. This then spread down into the left lower arm and hand, subsequently across her neck and down into the right arm as well. She describes pain and swelling in the left and right second fingers, diffusely through the finger, but with the pain mostly localized near the MCP (metacarpophalangeal) joint. The patient also noted some numbness and tingling as well as some burning in the hands. She has had some similar sensation in the feet as well. The patient has never had a flu shot in the past and this may have caused this pain.... She does have Volargen gel, but has not been using this regularly. She did see Dr. Fuller yesterday who feels that the myalgias are likely related to the flu vaccine and will likely resolve with time.

Ex. 4 at 43. Petitioner returned to Dr. Shih for a follow-up on October 14, 2015 complaining of worse pain in her hands and left arm. *Id.* at 42. Dr. Shih noted Petitioner was experiencing some pain in her wrists and there was swelling in her fifth finger in her right hand and had possible swelling in her wrists. *Id.* The pain in her hands was described as a “burning, numbness or tingling kind of sensation” and were so weak that she required two hands to lift a teapot. *Id.*

On November 6, 2015, Petitioner presented to Dr. Shih complaining of worse pain in her hands and left shoulder. *Id.* at 41. Dr. Shih noted there was some swelling in the “second and fifth digits of the right hand.” *Id.* Petitioner also had difficulty making a fist that morning. *Id.* Dr. Shih stated that Petitioner’s symptoms suggested inflammatory arthritis but paresthesia was suggestive of carpal tunnel syndrome. *Id.*

Petitioner saw Dr. Donny Chang, who specializes in endocrinology, on November 16, 2015 for a follow-up regarding her prediabetes. Ex. 4 at 38-40; Ex. 8 at 4-5. Dr. Chang did not note anything regarding Petitioner’s pain.

On December 3, 2015, Petitioner saw her PCP, Dr. Fuller, for an urgent visit. Ex. 4 at 32. Petitioner reported

an 11 week history of problems with both arms and rotator cuff tendinitis/tear. She reports that her problems began when she got a flu shot at CVS on November [sic] 18th. She is in a great deal of pain. At night, she cannot sleep. Her symptoms are getting worse. She has decreased sensation in her right hand and left hand also as well as the arm. Her rheumatologist has ordered an MRI of her shoulder and this showed a low-grade partial intrasubstance tear of the infraspinatus and mild supraspinatus tendinopathy. An EMG showed carpal tunnel, but she is feeling frustrated because she was expecting to have an EMG of both arms and it was just the wrist and hand area that was evaluated. I had diagnosed her with tennis elbow, but she does not feel that this is an issue at this time. Her right hand has been swollen for two months. Her neck has locked up, and this began around October or November. She has been seeing the chiropractor every week.<sup>5</sup> She has been there about three times. The neck is better, but both arms are terrible, she reports.

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<sup>5</sup> No chiropractic records have been filed.

*Id.* Dr. Fuller noted that the differential diagnosis was not clear, but that Petitioner's pain was inconsistent with the MRI. *Id.* Petitioner was prescribed an increase dosage of Vicodin and referred for an MRI and x-ray. *Id.* Petitioner was to follow-up with Dr. Michael Brown, who specializes in orthopedics, "for her left shoulder rotator cuff and neurology to evaluate her pain issue, question vaccine related myelopathy." *Id.*

On December 11, 2015, Petitioner saw Dr. Jordan Eisenstock at Community Neuroscience Services with complaints of "arm pain/ s/p [status post] flu shot". Ex. 4 at 29; Ex. 7 at 9. Dr. Eisenstock noted that

The patient states that her current problem started when she received a flu shot on November 18.<sup>6</sup> Since that time she's been in great pain, initially involving just the left upper extremity but then spreading to the right upper extremity as well. She did have an MRI of her left shoulder which showed partial tear of the infraspinatus and supraspinatus tendinopathy. An EMG later showed bilateral carpal tunnel syndrome but no other significant findings. Her pain is now greatly debilitating and very limiting... she has continued to have migraines for many years and states that the frequency is actually increased recently because of all of the stress.

Ex. 4 at 29; Ex. 7 at 9. Dr. Eisenstock reviewed a C-spine MRI and noticed "some disc bulging and some CSF (cerebrospinal fluid) changes but I suspect only reminiscent of DJD [degenerative joint disease] and not a larger problem." Ex. 4 at 30; Ex. 7 at 10. Dr. Eisenstock assessed Petitioner as having "nerve root and plexus disorder, unspecified" and migraines. Ex. 4 at 30, Ex. 7 at 10. Dr. Eisenstock also noted that "Patient's a picture [sic] many symptoms appear to be temporarily correlated with flu vaccine. I wonder if there was an underlying vulnerability or predisposition but blood work and examination have largely been unrevealing. Well underlying etiology is uncertain treatment for a possible comp which regional pain syndrome or simply neuropathic pain, NOS [not otherwise specified], is most likely indicated." Ex. 4 at 30; Ex. 7 at 10. Dr. Eisenstock started Petitioner on Topiramate. Ex. 4 at 30; Ex. 7 at 11.

On December 14, 2015, Petitioner presented to Drs. Hanbing Zhou and Michael Brown with bilateral shoulder pain, left worse than right. Ex. 4 at 24. The records note that

she had a flu shot on September 18, 2015 on the left shoulder, she has significant shoulder pain on both sides started on the left side since the flu shot, but now the right side is bothering her as well. The patient does report a numbness as well tingling as well as burning sensation in the C5-C6 distribution on occasions. The patient reports significant amount of pain 9-10/10 with any sort of overhead activities since flu shot. The patient reports the weakness she experiences secondary to pain. The patient also reports cervical radiculopathy symptoms where there is shooting pain coming from her neck and it travels to the posterior scapula and along the posterior aspect of the both of her arms.

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<sup>6</sup> The vaccine was administered on September 18, 2015.

*Id.* Drs. Zhou and Brown reviewed Petitioner's MRIs and found that she had bilateral shoulder inflammation on the left side and a very low-grade partial tear of the infraspinatus and a herniated disk at the C5-C6 level. *Id.* at 25. Petitioner was injected with Marcaine with Depo-Medrol for "rotator cuff inflammation of both shoulders". *Id.* Drs. Zhou and Brown also recommended that Petitioner begin physical therapy. *Id.*

Petitioner saw Dr. Michael Stauff on January 4, 2016. Ex. 4 at 18-19. Dr. Stauff, an orthopedist, reviewed her cervical MRI and observed disc degeneration and spondylosis at C5-C6 with mild central and bilateral foraminal stenosis. *Id.* at 19. Dr. Stauff also noted that "I have no explanation for why her symptoms cropped up after her flu shot. She has no radicular or myelopathy symptoms. She has neck pain associated with disk [sic] degeneration. I recommend activity based treatment and nonnarcotic pain medication. I have given her a prescription for therapy." *Id.*

On January 12, 2016, Petitioner saw Alixis Vanhorn, A.R.N.P., for arm, shoulder, and back pain. Ex. 4 at 14; Ex. 7 at 4. N.P. Vanhorn noted the same symptoms as documented in Petitioner's other medical records. N.P. Vanhorn gave Petitioner a prescription for OT/PT and advised her to get regular neck and back massages, use ice, and avoid positions which exacerbate pain. Petitioner returned to N.P. Vanhorn on February 12, 2016. Ex. 4 at 12; Ex. 7 at 14. The reason for appointment was "arm and hand pain" and "paresthesia of UE's". Ex. 4 at 12; Ex. 7 at 14. N.P. Vanhorn noted

paresthesia and numbness and weakness in UE's bilat, R>L. Referred to and seen in OT/PT, got splints to wear at night that help with pain; pain in back persistent.... Has been biking at gym, doing PT exercises on her own. Continues with significant pain in hands bilat, especially thumb and pointer finger.

Ex. 4 at 12; Ex. 7 at 14.

Petitioner returned to Community Neuroscience Services on February 24, 2016 to see Dr. Eisenstock. Ex. 4 at 7; Ex. 7 at 17. Petitioner noticed that the injections she received in December 2015 "significantly improved her pain for a period of time. Unfortunately the pain has since returned and she is not in the same excruciating pain is only [sic] first met but still very uncomfortable at this moment." Ex. 4 at 7; Ex. 7 at 17. Dr. Eisenstock increased the dosage of Petitioner's Topiramate prescription for neuropathic pain management and migraines. Ex. 4 at 8; Ex. 7 at 18.

On March 7, 2016, Petitioner had a follow-up appointment with Dr. Fuller for her medication. Ex. 4 at 6. Petitioner's symptoms remained consistent, with notes of some relief after cortisone injections in both shoulders. Petitioner indicated she needed another round of injections. *Id.* Petitioner reported she has hand pain all day and "feels like her fingers get swollen, but no one can see it." *Id.* Dr. Fuller assessed Petitioner with cervical radiculopathy, temporomandibular joint pain and migraines. *Id.*

On March 11, 2016, Petitioner followed up with Dr. Eisenstock. Ex. 4 at 3; Ex. 7 at 19. Petitioner relayed to Dr. Eisenstock that she was experiencing increased shortness of breath and

possible over-sedation. Ex. 4 at 3; Ex. 7 at 19. Dr. Eisenstock decreased Petitioner's Topiramate dosage and started her on Lamictal for pain. Ex. 4 at 4; Ex. 7 at 20.

Petitioner met with Dr. Ross to follow up on her thyroid cancer. Ex. 5 at 8. In an "other problems" section, Dr. Ross noted "Brachial neuritis after a flu shot, but bilateral (the second started a couple of weeks later)". *Id.* at 9. No other notations were made about Petitioner's pain.

On March 17, 2016, Petitioner met with Mary Seguin, N.P., for bilateral shoulder pain. Ex. 4 at 1. Petitioner requested and received two corticosteroid injections in her shoulders with Dr. Brown's permission. *Id.*

On May 11, 2016, Petitioner met with Dr. Eisenstock for a follow-up appointment. Ex. 7 at 22. There were no adjustments made to her medication because she was unable to tolerate a higher dose, but the records indicate the medications were "otherwise helping". *Id.* at 22-23.

Petitioner returned to Dr. Eisenstock on October 5, 2016 to review her medications. Ex. 10 at 8. Petitioner informed Dr. Eisenstock of increased numbness and tingling in both of her hands and fifth digits of both hands. *Id.* Petitioner also said injections have had "up-and-down benefits" but help with the pain. *Id.* On physical examination, Petitioner "did have positive Tinel's<sup>7</sup> and both medial epicondyles<sup>8</sup> of the elbows.... She had negative Tinel's though at both wrists. There was no obvious thenar or hyperthenar atrophy." *Id.* at 9.

On February 6, 2017, Petitioner saw Dr. Eisenstock to discuss obtaining another EMG. Ex. 10 at 3. Petitioner's symptoms remained largely unchanged, but she had questions regarding ulnar neuropathies. *Id.* Petitioner informed Dr. Eisenstock that she could probably tolerate an increase in dosage of Lamictal but was in the process of obtaining a GI workup for elevated liver enzymes. *Id.* Dr. Eisenstock did not recommend an increased dose until her GI workup returned. *Id.* at 3-4.

On March 3, 2017, Petitioner saw Breta Boots, D.O., with complaints of "tingling and pain in the upper extremities bilaterally, left greater than right, extending from elbow to forearm and involving all 5 fingers, also left greater than right." Ex. 10 at 11. Dr. Boots reviewed Petitioner's EMG and opined it was "mildly abnormal". *Id.* The EMG showed

There is electrophysiological evidence of median nerve mononeuropathy (as can be seen in carpal tunnel syndrome) at the wrists bilaterally which is mild in severity on the left and minimal on the right. There is no evidence of any other superimposed

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<sup>7</sup> Tinel's is "a tingling sensation in the distal end of a limb when percussion is made over the site of a divided nerve. It indicates a partial lesion or the beginning regeneration of the nerve." *Tinel sign*, DORLAND'S MEDICAL DICTIONARY ONLINE (hereinafter "DORLAND'S"), <https://www.dorlandsonline.com/dorland/definition?id=106510> (last visited on December 14, 2020).

<sup>8</sup> An epicondyle is "an eminence on a bone above its condyle." *Epicondyle*, DORLAND'S, <https://www.dorlandsonline.com/dorland/definition?id=16789> (last visited on December 16, 2020). A condyle is "a rounded projection on a bone, usually for articulation with another." *Condyle*, DORLAND'S, <https://www.dorlandsonline.com/dorland/definition?id=10794> (last visited on December 16, 2020).

mononeuropathies (i.e. ulnar nerve, radial nerve) in either upper extremity. Needle examination reveals some mild, likely chronic, changes in a few muscles in the left upper extremity which could raise the possibility of a very mild left-sided cervical radiculopathy at the level of C7-8.

*Id.* at 11-12.

Petitioner followed up with Dr. Eisenstock on March 6, 2017. Ex. 10 at 1. Dr. Eisenstock reviewed Petitioner's EMG and found it showed some chronic innervation changes in the lower cervical area, mild carpal tunnel bilaterally and no findings of ulnar neuropathy. *Id.* He informed Petitioner that "no additional intervention is required other than neuropathic pain management." *Id.* at 2.

### **III. Affidavit**

Petitioner filed an affidavit on April 10, 2017, which she signed on October 18, 2016. Ex. 2. Petitioner stated she felt immediate pain after the flu vaccine which spread down her arm all the way to her hand. Ex. 2 at 1. The pain was so severe that she "was unable to lift [her] arm to take [her] clothes off." *Id.* Petitioner added that, "[t]he pain then spread across my back and into my right shoulder and arm." *Id.* Petitioner stated that she required assistance from her husband with normal activities like dressing and pulling the covers off to get out of bed. *Id.* Mr. LaBounty also drove Petitioner to medical appointments and to work when she was unable to because of the pain. *Id.*

Petitioner stated she was diagnosed with brachial neuritis and underwent two rounds of physical therapy with minimal improvement. Ex. 2 at 2. Petitioner indicated that she was fully employed but had to take time off for her symptoms and took medication that made her very forgetful. *Id.* Petitioner stated that "[m]any aspects of [her] life have been negatively affected by this injury." *Id.*

On January 15, 2019, Petitioner submitted a supplemental affidavit. Ex. 13. Petitioner stated that since the vaccination, her feet and hands get very cold and her hands "get so cold that they actually hurt." *Id.* at 1. These were not symptoms she experienced prior to the vaccination. *See id.* Additionally, Petitioner stated "[t]hese specific symptoms occurred during the time of my severe back and neck pain." *Id.* Petitioner described these symptoms to her doctors as a "decreased sensation, because they feel numb when cold." *Id.*

### **IV. Expert Opinions**

#### **A. Dr. Marcel Kinsbourne**

Petitioner filed an expert report and three supplemental reports from Dr. Kinsbourne. Exs. 11 ("First Kinsbourne Rep."), 15 ("Second Kinsbourne Rep."), 16a ("Third Kinsbourne Rep."), 17 ("Fourth Kinsbourne Rep.").

Although no curriculum vitae was submitted for Dr. Kinsbourne, I am aware from previous cases that Dr. Kinsbourne received his medical degree from Oxford University in 1955. *See Bryan v. Sec’y of Health & Hum. Servs.*, No. 14-898, 2020 WL 7089841, at \*12 (Fed. Cl. Spec. Mstr. Oct. 9, 2020). Dr. Kinsbourne completed post-doctoral training in neurology and pediatrics and is Board Certified in Pediatrics. *See id.* Dr. Kinsbourne has had a number of hospital and academic appointments and has been a research professor at the Center for Cognitive Studies at Tufts University since 1992 and a Professor of Psychology at New School University since 1995. *Id.* Dr. Kinsbourne serves on numerous editorial boards, including Brain Research, Cognitive Neuropsychiatry, Journal of Psycholinguistic Research, and many others. *Id.* Dr. Kinsbourne has published over 400 articles regarding pediatrics and neurology. *Id.*

### 1. Dr. Kinsbourne’s First Report

In Dr. Kinsbourne’s first report, he summarized Petitioner’s symptoms as “severe neuropathic pain in the absence of focal neurological signs and without clear etiology.” First Kinsbourne Rep. at 2. Based on Petitioner’s initial symptom of severe pain around the injection site, the immediate onset suggested a SIRVA. *Id.* at 3. However, according to Dr. Kinsbourne, her pain became more widespread, leading to a possible diagnosis of brachial neuritis. *Id.*, *see also* Pet. However, Petitioner’s symptomology did not follow the typical disease trajectory because Petitioner did not develop muscle weakness. First Kinsbourne Rep. at 3.

Dr. Kinsbourne noted that Dr. Eisenstock entertained a CRPS diagnosis. First Kinsbourne Rep. at 3; *see also* Ex. 4 at 30; Ex. 7 at 10. Dr. Kinsbourne provided an overview of the signs and symptoms of CRPS and cited the International Association for the Study of Pain’s (“IASP”) criteria for a CRPS diagnosis. *See generally* First Kinsbourne Rep. at 3-4. Dr. Kinsbourne “confirmed” a CRPS diagnosis by stating:

*Presence of an initiating noxious event or a cause of immobilization.* Sharon LaBounty received an intramuscular injection of influenza vaccine.

*Continuing pain, allodynia or hypalgesia [sic] with which pain is disproportionate to any inciting event.* Her influenza vaccination triggered disproportionate pain.

*Evidence at some time of edema, changes in skin blood flow or abnormal sudomotor activity in the region of the pain.* She had swelling of her fingers.

*Diagnosis is excluded by existence of other conditions that would otherwise account for the degree of pain and dysfunction.* No such conditions (brachial neuritis, cervical spondylosis) could be corroborated.

*Id.* at 4. Dr. Kinsbourne also noted that the temporary help of corticosteroid injections corroborated the CRPS diagnosis. *See generally id.* at 4-5. Dr. Kinsbourne cited a 2003 case study in which four patients developed CRPS after receiving hepatitis B vaccinations. *Id.* at 5. In explaining how Petitioner’s vaccination caused her disease, Dr. Kinsbourne stated, “CRPS can be caused by vaccination with diverse vaccines, consistent with the view that it was mechanical

trauma due to the injection rather than a chemical effect due to a particular vaccine that caused the disorder.” *Id.*

## 2. Dr. Kinsbourne’s Second Report

Dr. Kinsbourne opined that the “Budapest criteria are an elaboration of the IASP format that subdivides the questionnaire items into those that are subjective and those that are observative.” Second Kinsbourne Rep. at 1. The IASP criteria “maximize sensitivity at the expensive of specificity” while the Budapest criteria are “far more conservative”. *Id.* Dr. Kinsbourne listed the four criteria (sensory, vasomotor, sudomotor, motor/trophic) and referenced the correlating records that satisfied these criteria:

1. Sensory: Pain from things that are not normally painful  
Ms. LaBounty had pain from joint movement; raising left arm above shoulder level. Also burning pain waking her at night. She was unable to dress herself, pull covers off the bed or drive, due to excessive pain (Affidavit, October 18, 2016)
2. Vasomotor  
Abnormally cold feeling in both hands (Affidavit, January 10, 2019)  
Fingers blanch (Exhibit 4, p. 32).
3. Sudomotor  
Edema; swelling dorsum of hands (Exhibit 4, p. 3, Exhibit 9, pp. 32, 43)
4. Motor/trophic  
Inability to move left arm  
Weakness both arms (Exhibit 4, pp. 10, 12, 32) weak right hand intrinsic muscles, weak abduction of fingers (Exhibit 4, p 11).

*Id.* at 2. Based on his interpretation of Petitioner’s records, Dr. Kinsbourne opined that she had CRPS pursuant to the Budapest criteria. *Id.* Regarding my question whether Petitioner showed symptoms of hyperesthesia and allodynia, Dr. Kinsbourne stated that Petitioner’s behavior “indicated” hyperesthesia of the affected limb and “allodynia is consistent with Ms. LaBounty’s actions, such as guarding her arm from perturbations”. *Id.* at 3.

Dr. Kinsbourne also responded to Dr. Callaghan’s first expert report. Dr. Kinsbourne did not address Petitioner’s previous diagnosis of central sensitization syndrome but cited medical literature regarding the relationship between CRPS and migraines. *See* Second Kinsbourne Rep. at 2-3. Dr. Kinsbourne added that Petitioner’s history of migraines and dysmenorrhea were risk factors for CRPS. *Id.* at 3. Dr. Kinsbourne maintained that the type of vaccine is irrelevant to the development of CRPS but that a needle-induced soft tissue injury could cause CRPS. *Id.*

## 3. Dr. Kinsbourne’s Third Report

Dr. Kinsbourne filed a third report to answer additional questions that I posed. Dr. Kinsbourne opined that Petitioner's CRPS began 15 minutes after the "needle-stick for the influenza vaccination" and that there was no medically appropriate onset interval for CRPS after needle stick but cited medical literature that showed that onset was "immediate after the injury". Third Kinsbourne Rep. at 1. Dr. Kinsbourne restated his position that Petitioner met both the IASP and the Budapest criteria. He further clarified that Petitioner's finger blanching did not constitute a color change for purposes of the criteria but "is secondary to vasomotor dysregulation". *Id.* at 2. Finally, Dr. Kinsbourne stated that the symptoms of CRPS do wax and wane over time. *Id.* at 3-4.

#### 4. Dr. Kinsbourne's Fourth Report

Dr. Kinsbourne copied his assessment of the Budapest criteria from his first supplemental report and restated his opinion that Petitioner met the four categories of the criteria. Fourth Kinsbourne Rep. at 1-2.

### **B. Dr. Brian Callaghan**

Respondent filed an expert report and two supplemental reports from Dr. Callaghan. Exs. A ("First Callaghan Rep."), C ("Second Callaghan Rep."), D ("Third Callaghan Rep.").

Dr. Callaghan received his medical degree from the University of Pennsylvania in 2004. Ex. B (hereinafter "Callaghan CV") at 1. Dr. Callaghan completed his residency in neurology at the University of Pennsylvania and completed two fellowships at the University of Michigan. *Id.* Dr. Callaghan is board certified in neurology and electrodiagnostic medicine. *Id.* He is a professor at the University of Michigan, Ann Arbor and VA Ann Arbor Healthcare system. *Id.* Dr. Callaghan is the director of the ALS Clinic and a Staff Physician in the Department of Neurology at the VA Ann Arbor Health System. *Id.* at 1-2. Dr. Callaghan is actively involved in research, is on the editorial board of Innovations in Care Delivery (Neurology) and is a journal reviewer for an extensive number of publications including but not limited to Annals of Neurology, Brain, Brain and Behavior, Diabetes, Lancet, Neurology. *Id.* at 3-5. Dr. Callaghan has published over 70 peer reviewed papers and book chapters. He has presented at many conferences and institutions, both nationally and internationally. *Id.* at 6-15.

#### 1. Dr. Callaghan's First Report

Dr. Callaghan opined that the Budapest Criteria are "the most accepted diagnostic criteria for the diagnosis of CRPS." Resp't's Status Rep. on 4/7/2020, ECF No. 47. The Budapest Criteria require that a patient have three of four categories of symptoms (sensory, vasomotor, sudomotor/edema, and motor/trophic) and two of four signs (sensory, vasomotor, sudomotor/edema, motor/trophic). First Callaghan Rep. at 2. Dr. Callaghan stated that CRPS should only be considered when there is no better alternative diagnosis available. *Id.* Dr. Callaghan indicated that Petitioner's diagnosis of central sensitization syndrome, or chronic overlapping pain conditions, was correct and that Petitioner's symptoms correlate best with this diagnosis. *Id.* at 2-3. Petitioner's extensive history of migraines, temporal mandibular joint pain,

low back pain, and irritable bowel syndrome indicate that she has central sensitization syndrome and Petitioner's post-vaccination arm pain qualifies as a chronic overlapping pain condition. *Id.*

Additionally, Dr. Callaghan stated that there has not been any epidemiological support to show that a flu vaccination can cause CRPS. The few case studies filed by Petitioner provide a small sample size and do not apply to this case because different vaccines were involved in the case studies. First Callaghan Rep. at 3.

## 2. Dr. Callaghan's Second Report

Dr. Callaghan reiterated that Petitioner does not meet the criteria for CRPS because she has experienced pain since 2008 and was diagnosed with central sensitization syndrome which "better explains her signs and symptoms". Second Callaghan Rep. at 2. Petitioner's extensive pain history which included fibromyalgia, migraines, low back pain, temporal mandibular joint pain, and irritable bowel syndrome, is consistent with central sensitization syndrome. *Id.* While Petitioner had migraines and dysmenorrhea, which are risk factors for CRPS, she had other chronic pain conditions. *Id.* Dr. Callaghan also stated that Dr. Kinsbourne provided no evidence to support his theory of causation other than case reports, however "these are the lowest form of epidemiologic support." *Id.* at 1-2.

## 3. Dr Callaghan's Third Report

Dr. Callaghan submitted his third and final report answering additional questions that I posed. Dr. Callaghan stated that Petitioner did not meet the Budapest Criteria for CRPS because she exhibited neither vasomotor nor sudomotor/edema symptoms. Third Callaghan Rep. at 1. The Budapest criteria require a patient to meet three out of four categories of symptoms and two out of four categories of signs. Dr. Callaghan disputed Dr. Kinsbourne's assessment of coldness in Petitioner's hands as a vasomotor symptom. *Id.* Dr. Callaghan also noted that Petitioner experienced a mild edema, which was "not a symptom". *Id.* Important in the Budapest criteria are the asymmetry of symptoms. Petitioner did not exhibit temperature asymmetry, skin color asymmetries, or trophic changes (skin, hair, nails). *Id.*

Regarding needle stick, Dr. Callaghan opined that he did not believe needle sticks are sufficient to cause CRPS. *Id.* He cited medical literature that noted triggers for CRPS included "fractures, sprains, contusions, crush injuries and surgeries" with fractures (42%), blunt traumatic injuries (21%), and surgery (12%) the most common causes of CRPS. *Id.* With regards to the case reports that Dr. Kinsbourne cited, Dr. Callaghan noted none were after a seasonal flu vaccination and in one of the articles, it found no increase in the observed and expected numbers of CRPS after HPV vaccination. *Id.* It is Dr. Callaghan's opinion that CRPS cannot be caused by needle stick and even if it could, Petitioner did not have CRPS. *Id.* at 2.

Dr. Callaghan next opined that the symptoms of CRPS do not wax and wane, as Petitioner's symptoms did. Third Callaghan Rep. at 2. CRPS can worsen and improve over time but would not have dramatic changes month to month. *Id.* Furthermore, CRPS is unlikely to respond to treatments for shoulder pain (steroid shots) or carpal tunnel syndrome (splints), which Petitioner received. *Id.*

## V. Applicable Law

### A. Petitioner's Burden in Vaccine Program Cases

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a “Table” injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). “In such a case, causation is presumed.” *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an “off-Table” injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. § 13(1)(a). That is, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [she] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also* *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his injury “by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Id.* at 1278.

Under the first prong of *Althen*, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is reasonable, plausible, or possible does not satisfy a petitioner’s burden. *Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1359-60 (Fed. Cir. Nov. 7, 2019).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical

theory. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are “entitled to require some indicia of reliability to support the assertion of the expert witness.” *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec’y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec’y of Health & Hum. Servs.*, No. 17-168V, 2020 U.S. Claims LEXIS 2202 at \*52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician’s views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing ... that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec’y of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at \*17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den’d*, 100 Fed. Cl. 344, 356 (2011), *aff’d without opinion*, 475 Fed. App’x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant

vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

## **B. Law Governing Analysis of Fact Evidence**

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are presumed to be accurate and “complete” such that they present all relevant information on a patient's health problems. *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law”), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at \*2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), *mot. for review den'd* (Fed. Cl. Feb. 11, 2019), *vacated on other grounds*, 809 Fed. Appx. 843 (Fed. Cir. 2020); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) (“[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.”).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396

(1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec’y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475, at \*19 (“[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent and compelling.” *Sanchez*, 2013 WL 1880825, at \*3 (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *LaLonde v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

### C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). See *Cedillo v. Sec’y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec’y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). “The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.” *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude

evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec’y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g., Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner’s case. Where both sides offer expert testimony, a special master’s decision may be “based on the credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert’s conclusion “connected to existing data only by the *ipse dixit* of the expert,” especially if “there is simply too great an analytical gap between the data and the opinion proffered.” *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A “special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert’s credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations”); *see also Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) (“this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act”).

#### **D. Consideration of Medical Literature**

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec’y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) (“We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision.”); *Simanski v. Sec’y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) (“[A] Special Master is ‘not required to discuss every piece of evidence or testimony in her decision.’” (citation omitted)), *aff’d*, 601 F. App’x 982 (Fed. Cir. 2015).

### **VI. Analysis**

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, her claim is classified as “off-Table.” As noted above, to prevail on an “off-Table” claim, Petitioner must prove by preponderant evidence that she suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

## A. CRPS Generally

CRPS is a chronic pain condition “characterized by spontaneous and evoked regional pain”. S. Bruehl, *Complex regional pain syndrome*, BMJ at 1 (2015) (filed as Ex. E). CRPS generally begins in an extremity and the pain experienced is disproportionate to the injury. *Id.* The typical characteristics of CRPS include continuous pain, sensory, vasomotor, sudomotor/edema, and motor/trophic signs and symptoms. Ott & Maihöfner, *Signs and Symptoms in 1,043 Patients with Complex Regional Pain Syndrome*, 19 THE JOURNAL OF PAIN 6, 599-611 (2018) (filed as Ex. F) (hereinafter “Ott & Maihöfner”). CRPS pain has been described as “‘burning,’ ‘pins and needles’ sensation, or as if someone were squeezing the affected limb.” *Complex Regional Pain Syndrome Fact Sheet*, National Institutes of Neurological Disorders and Stroke, National Institutes of Health (filed as Ex. 11c) (hereinafter “NIH Fact Sheet”). CRPS can also travel to the opposite extremity. *Id.* at 1. In the initial acute stage of CRPS, “inflammation is common and can be targeted with corticosteroid therapy.” See M. Ferguson, *Steroids for Complex Regional Pain Syndrome?*<sup>9</sup>

The cause of CRPS is unknown. The NIH Fact Sheet estimates that 90% of CRPS cases are triggered by trauma or an injury. NIH Fact Sheet at 2. The severity of trauma is not linked to the development of CRPS. Marinus et al., *Clinical features and pathophysiology of complex regional pain syndrome*, THE LANCET NEUROLOGY, vol. 10, 637-648 (2011) (filed as Ex. 15d) (hereinafter “Marinus”). It is generally understood that CRPS is a disorder associated with “an aberrant host response to tissue injury.” *Id.* at 1.

## B. Petitioner Has Carried Her Burden of Proof

### 1. There is Preponderant Evidence that Petitioner Suffers from CRPS

The first step in an “off-Table” claim is to “determine what injury, if any, was supported by the evidence presented in the record.” *Lombardi v. Sec’y of Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). The Vaccine Act “places the burden on the petitioner to make a showing of at least one defined and recognized injury,” and “[i]n the absence of a showing of the very existence of any specific injury[,] . . . the question of causation is not reached.” *Id.*; see *Broekelschen*, 618 F.3d at 1346 (explaining that “identifying the injury is a prerequisite to the [causation] analysis”). In this case, there is a dispute as to whether Petitioner suffered from CRPS.

In order to be diagnosed with CRPS, a patient must have continuing pain disproportionate to any inciting event, display the signs and symptoms enumerated in the Budapest Criteria, and establish that no other diagnosis better explains the patient’s signs and symptoms.

#### a. *Diagnostic Criteria*

Both experts agree that the Budapest Criteria are an appropriate diagnostic standard for

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<sup>9</sup> <https://www.practicalpainmanagement.com/treatments/pharmacological/non-opioids/steroids-complex-regional-pain-syndrome#fieldset>; (filed as Ex. 11f) (last accessed December 15, 2020).

CRPS. *See* Second Kinsbourne Rep. at 1-2; Resp't's Status Rep. dated April 7, 2020, ECF No. 47. The Budapest Criteria were discussed in a 2007 article by Harden et al.<sup>10</sup> The criteria include:

- 1) Continuing pain, which is disproportionate to any inciting event
- 2) Must report at least one symptom<sup>11</sup> in three of the four following categories:
  - Sensory: reports of hyperesthesia and/or allodynia
  - Vasomotor: reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry
  - Sudomotor/edema: reports of edema and/or sweating changes and/or sweating asymmetry
  - Motor/trophic: reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
- (3) Must display at least one sign at time of evaluation in two or more of the following categories:
  - Sensory: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or deep somatic pressure and/or joint movement)
  - Vasomotor: evidence of temperature asymmetry and/or skin color changes and/or asymmetry
  - Sudomotor/edema: evidence of edema and/or sweating changes and/or sweating asymmetry
  - Motor/trophic: evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
- (4) There is no other diagnosis that better explains the signs and symptoms

i. Continuing Pain Disproportionate to any Inciting Event

The experts generally agree that Petitioner meets the first three criteria. First, Petitioner does have continuing pain, documented throughout her medical records which is disproportionate to the needle stick on September 18, 2015. In fact, Dr. Fuller described her pain as an “[e]xtreme increase in her arm and shoulder pain out of proportion to what is seen on MRI of the left shoulder.” Ex. 4 at 32.

ii. Reported Symptoms

Petitioner also described symptoms in three of the four categories as required by the second criterion. Dr. Kinsbourne opined and Dr. Callaghan conceded that Petitioner does have the sensory symptom of allodynia. *See* Second Kinsbourne Rep. at 2; Third Kinsbourne Rep. at 3; Fourth Kinsbourne Rep. at 1; Third Callaghan Rep. at 1.

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<sup>10</sup> Harden et al., *Proposed New Diagnostic Criteria for Complex Regional Pain Syndrome*, 8 PAIN MEDICINE 4 (2007) (filed as Ex. 15c).

<sup>11</sup> A sign is defined as “an indication of the existence of something; any objective evidence of a disease, i.e., such evidence as is perceptible to the examining physician, as opposed to the subjective sensations (symptoms) of the patient.” *Sign*, DORLAND’S, <https://www.dorlandsonline.com/dorland/definition?id=45805> (last visited on December 16, 2020).

In addition, Petitioner satisfied the sudomotor category based on the report of edema in her medical records. Dr. Callaghan disagreed with this point indicating that Petitioner's medical record describes signs and not symptoms of edema. *See* Third Callaghan Rep. at 1. While true for the particular record that he referenced (Ex. 4 at 32), there are other medical records where Petitioner discussed swelling of her hands that was not observed by her doctor. For example, during her visit with Dr. Eisenstock on March 11, 2016, the HPI states, "After her injections [s]he states that there was a significant relief of symptoms involving her left upper extremity and that she also notices some swelling in her hands had been improved." Ex. 4 at 3. There was no swelling documented on exam during this visit. On October 14, 2015, Petitioner described swelling in her right fifth finger and her wrists. *Id.* at 42. Additionally, during a September 30, 2015 visit with Dr. Shih, the subjective section of the record states, "She describes pain and swelling in the left and right second fingers, diffusely through the finger..." Ex. 9 at 43. The physical exam portion of the record indicates Petitioner had "[g]ood range of motion of elbows, wrists, fingers with no active synovitis." *Id.* Based on the foregoing, I find that Petitioner has experienced symptoms of edema.

I agree with Dr. Callaghan that there is not evidence Petitioner experienced vasomotor symptoms consistent with the Budapest Criteria (reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry). Dr. Kinsbourne initially opined that Petitioner met this criterion due to her "abnormal[] cold feeling in both hands" and the fact that her "fingers blanch". *See* Second Kinsbourne Rep. at 2. While Petitioner did describe that her hands were cold, she did not describe temperature asymmetry. In addition, I specifically asked Dr. Kinsbourne whether blanching of the fingers due to swelling constitutes a color change. He responded, "Not in the sense called for by diagnostic criteria. A color change should characterize the skin of the affected limb independent of swelling. Blanching is secondary to vasomotor dysregulation..." *Id.*

Finally, I find that Petitioner also experienced motor symptoms. Petitioner made several reports of pain with overhead movement throughout her medical records. For example, Petitioner visited Dr. Zhou on December 14, 2015. This record notes that she reported "significant amount of pain 9-10/10 with any sort of overhead activities since the flu shot." Ex. 4 at 24. On September 30, 2015, Dr. Shih noted that Petitioner "has pain with full abduction of both shoulders, as well as external and internal rotation..." *Id.* at 43. Further, Dr. Callaghan agreed that Petitioner did experience motor symptoms which included pain with movement and pain limiting movement. Third Callaghan Rep. at 1.

The Budapest criteria require that Petitioner experience at least one symptom in three of the four categories. The above analysis demonstrates that Petitioner has met the requirements of the second criterion.

### iii. Documented Signs

I find that the medical records document that Petitioner displayed signs in two of the four categories of the Budapest Criteria: sudomotor/edema and motor/trophic.

On December 3, 2015, Petitioner visited Dr. Fuller. Dr. Fuller conducted a physical examination and noted that “[t]here is mild swelling of the dorsum of the right hand and fingers compared with the left side.” Ex. 4 at 32. Both Dr. Kinsbourne and Dr. Callaghan agree that this documented instance of edema constitutes a sudomotor sign. *See* First Kinsbourne Rep. at 4; Second Kinsbourne Rep. at 2; Fourth Kinsbourne Rep. at 1; Third Callaghan Rep. at 1.

On February 12, 2016, Petitioner visited N.P. Vanhorn. On physical examination, N.P. Vanhorn noted “some discomfort on PROM at shoulder and with abduction of fingers.” Ex. 4 at 11. She also noted “Normal strength except some slight (5-/5) in right hand intrinsics and in finger abduction, R>L.” *Id.* On December 3, 2015, Dr. Fuller noted the following on physical exam:

There is discomfort around the deltoid muscle of the right shoulder. There is decreased sensation to light touch over the left upper extremity laterally and a mild decreased sensation in the left hand and numbness in the right hand. DTRs 1 + bilaterally in the arms. There is decreased power, about 4/5 bilaterally. There is some mild discomfort to palpation in the cervical paravertebral areas.

*Id.* at 32. Dr. Kinsbourne opined that each of these examples from the medical records constitute examples of motor signs. *See* Second Kinsbourne Rep. at 2; Fourth Kinsbourne Rep. at 1. Dr. Callaghan also agreed that Petitioner experienced motor signs which included pain with movement and pain limiting movement. Third Callaghan Rep. at 1.

The Budapest criteria require that Petitioner experience at least one sign in two of the four categories. The above analysis demonstrates that Petitioner has met the requirements of the third criterion.

iv. There is No Other Diagnosis that Better Explains the Signs and Symptoms

The only question that remains is whether Petitioner has another diagnosis that better explains her signs and symptoms. Dr. Callaghan has opined that Petitioner’s diagnosis of central sensitization syndrome explains her signs and symptoms and precludes a diagnosis of CRPS. In describing central sensitization syndrome, he stated:

Another term used for this disorder is chronic overlapping pain conditions, which includes fibromyalgia, migraines, low back pain, temporal mandibular joint pain, and irritable bowel syndrome. She had all of these conditions as documented above. Therefore, by far the most likely cause of her unexplained bilateral arm pain is a chronic overlapping pain condition such as fibromyalgia or myofascial pain syndrome.<sup>12</sup>

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<sup>12</sup> Dr. Kinsbourne responded by stating there is not evidence in the medical records that Petitioner met the diagnostic criteria for either fibromyalgia or myofascial pain syndrome. Second Kinsbourne Rep. at 3. In response, Dr. Callaghan wrote as follows: “Dr. Kinsbourne notes that she does not meet formal criteria for fibromyalgia or myofascial pain syndrome. While correct that no one formally investigated whether she

First Callaghan Rep. at 1-2.

Dr. Callaghan cited to the April 18, 2014, visit with Raymond Pertusi, D.O. as support for his opinion that Petitioner's central sensitization syndrome explained her signs and symptoms. In the HPI section of this record, Dr. Pertusi noted that:

This 49 YO F, a patient of Dr. I. Fuller, saw her on 3/26/14 and was noted to have joint pains. Question OA vs. autoimmune?<sup>13</sup> if she has Raynaud's. Does she have a rheumatologic issue?

Her pain began about 2008. It's all day every day but worse in the morning. Less dietary gluten helps. It's aching. No radiation. It's moderately severe. Joints/areas affected include all 4 quadrants: ankles, knees, hands, shoulders, neck, LB, and hips. She has fatigue, cramping, and numbness in fingers and toes. Her 1-3 fingers do turn white on cold exposure.

Ex. 4 at 80. After an examination, Dr. Pertusi's impression was "Her pain generator is likely a central sensitization syndrome that could be related to remote trauma (Abuse X 3) and likely PTSD." Ex. 4 at 82.

I will note that aside from the description in Dr. Callaghan's expert report cited above, there is no further information that explains central sensitization syndrome (or chronic overlapping pain conditions). There is no discussion of the syndrome's diagnostic criteria. No medical literature has been filed in this case which addresses the condition. As a result, it is difficult to assess whether Dr. Pertusi's impression in 2014 that Petitioner's "pain generator is likely a central sensitization syndrome" precludes a CRPS diagnosis.

Further, the opinions of Petitioner's treating neurologist help to inform this issue. After examining Petitioner on December 11, 2015, Dr. Eisenstock, found that her "many symptoms appear to be temporarily correlated with flu vaccine." Ex. 4 at 30. Dr. Eisenstock further found that treatment for "regional pain syndrome"<sup>14</sup> was indicated. *Id.* He prescribed Topiramate for

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met criteria, she still has a central sensitization syndrome as clearly documented in her medical record many years prior to her shoulder/arm pain (Exhibit 4, page 80)." Second Callaghan Rep. at 1.

<sup>13</sup> The fact that Dr. Pertusi questioned whether Petitioner's joint pain was from osteoarthritis or from an autoimmune disease raises a question as to whether a diagnosis of osteoarthritis and/or autoimmune disease is consistent with the impression of central sensitization syndrome. It is difficult to put this notation in context as no additional information on central sensitization syndrome has been filed.

<sup>14</sup> In his first expert report, Dr. Kinsbourne stated that regional pain syndrome was CRPS. First Kinsbourne Rep. at 2. As Dr. Callaghan did not contradict this statement, I presume it is true.

Petitioner's neuropathic pain. *Id.* Topiramate is a drug generally used to treat seizures.<sup>15</sup> The NIH Fact Sheet indicates that treatment for CRPS can include, among other medications, drugs initially developed to treat seizures which have now been demonstrated as effective in treating neuropathic pain. NIH Fact Sheet at 4. Dr. Eisenstock did not diagnose Petitioner with central sensitization syndrome or mention anything about a prior central sensitization syndrome diagnosis. Although Dr. Eisenstock did not formally diagnose Petitioner with CRPS, his belief that it was appropriate to treat her for this condition constitutes strong support that this is in fact her correct diagnosis.

Further, in a letter dated September 21, 2018, Dr. Eisenstock wrote, "Given a correlation in time with receiving the flu shot, I would entertain the possibility of a related complex regional pain syndrome...." Ex. 12. Again, Dr. Eisenstock did not conclusively diagnose Petitioner with CRPS. However, he did state that he would entertain a connection between Petitioner's condition and her flu vaccine. Implicit in this statement is that Dr. Eisenstock believes CRPS to be a reasonable diagnosis. Also implicit in both Dr. Eisenstock's treatment of Petitioner in 2015 and in his letter from 2018 is that he does not entertain a diagnosis of central sensitization syndrome. Presumably Dr. Eisenstock, a neurologist, is aware of the diagnostic criteria for CRPS, and that there can be no other diagnoses that better explain a patient's signs or symptoms. The fact that Dr. Eisenstock considers CRPS to be a reasonable diagnosis suggests he does not believe Petitioner has another diagnosis which explains her pain.

For the reasons discussed above, I find by preponderant evidence that Petitioner did not have another diagnosis which better explained her signs and symptoms.

b. *Two of Petitioner's Pre-existing Conditions are a Risk Factors for CRPS*

In addition to meeting the diagnostic criteria, Petitioner has a well-documented history of pre-existing migraine headaches and dysmenorrhea, which provides further support that she suffers from CRPS. *See* Ex. 4 at 46; *Id.* at 55. Several pieces of medical literature filed in this case articulate a connection between migraines and CRPS. For example, Peterlin et al. reported that

(i) migraine occurs in a greater percentage of CRPS sufferers than expected in the general population; (ii) the onset of CRPS is reported earlier in those with migraine than in those without; and (iii) CRPS symptoms are present in more extremities in those CRPS sufferers with migraine compared with those without.

*Migraine may be a risk factor for the development of complex regional pain syndrome, Cephalalgia*; 30(2): 214–223 (2010) (filed as Ex. 15e). Additionally, de Mos et al., found that "a

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<sup>15</sup> Topiramate is "a substituted monosaccharide used as an anticonvulsant in the treatment of partial seizures." *Topiramate*, DORLAND'S, <https://www.dorlandsonline.com/dorland/definition?id=50310> (last accessed December 16, 2020).

medical history of migraine was associated with CRPS.” *Medical history and the onset of complex regional pain syndrome (CRPS)*, PAIN (2008), doi:10.1016/j.pain.2008.07.002 (filed as Ex. 16c) (hereinafter “de Mos”). de Mos also noted an association between CRPS and menstrual cycle abnormalities. *Id.* As Petitioner had both migraines and dysmenorrhea documented in her medical records, Dr. Kinsbourne noted that “Mrs. LaBounty’s migraine and dysmenorrhea were risk factors for CRPS.” Second Kinsbourne Rep. at 3. This point, when considered in conjunction with the other evidence presented in this case, including Dr. Eisenstock’s letter and treatment of Petitioner, and Dr. Kinsbourne’s opinion, preponderantly establish that CRPS is Petitioner’s correct diagnosis.

### C. *Althen* Prongs

I will address the *Althen* prongs in their order of significance based on the facts of this case.

#### 1. *Althen* Prong 1

In the context of the Program, “to establish causation, the standard of proof is preponderance of evidence, not scientific certainty.” *Langland v. Sec’y of Health & Hum. Servs.*, 109 Fed. Cl. 421, 441 (2013). Petitioner’s burden under *Althen*’s first prong is to provide a medical theory causally connecting the vaccination and the injury. *Id.* This theory must be sound and reliable. *Boatmon*, 941 F.3d at 1359. Petitioners need not precisely identify a causative mechanism to prove causation in fact as the “identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.” *Knudsen*, 35 F.3d at 543.

As described by extensive literature and confirmed by both experts, the exact mechanism for onset of CRPS is yet unknown. “CRPS represents an abnormal response that magnifies the effects of the injury.” NIH Fact Sheet at 2. Minor trauma can amplify cytokine signaling; “cytokines and nerve growth factor can excite nociceptors and induce long-term peripheral sensitisation.” *Marinus* at 640. Generally, CRPS can develop after a surgery, traumatic event, or even a non-traumatic minor injury. Dr. Kinsbourne has stated that CRPS can occur following needle stick.

Dr. Kinsbourne’s opinion is generally supported by the literature filed in this case.<sup>16</sup> According to the Complex Regional Pain Syndrome Fact Sheet, published by the National Institutes of Neurological Disorders and Stroke<sup>17</sup>, in more than 90% of cases, CRPS is triggered by “a clear history of trauma or injury.” NIH Fact Sheet at 2. The fact sheet goes on to state that “the most common triggers are fractures, sprains/strains, soft tissue injury (such as burns, cuts, or

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<sup>16</sup> I also note that in a prior CRPS case that I adjudicated, I mentioned the opinion of Respondent’s expert, Dr. Phillip Low that “CRPS is well-documented after needle.” *Dixon Jones v. Sec’y of Health & Hum. Servs.*, No. 14-934V, 2019 WL 7556374, at \*26 (Fed. Cl. Spec. Mstr. Sept. 4, 2019). The testimony from that published decision is consistent with the medical literature referenced in this Ruling.

<sup>17</sup> The National Institutes of Neurological Disorders and Stroke is an institute within the National Institutes of Health. See <https://www.ninds.nih.gov/About-NINDS>. (Last accessed December 14, 2020).

bruises), limb immobilization (such as being in a cast), surgery, or even minor medical procedures such as needle stick.” *Id.* An additional piece of medical literature notes that “[t]he onset of CRPS is usually linked to a history of trauma, immobilization, or a procedure such as venipuncture, intramuscular injection, or surgery.” Raja and Grabow, *Complex Regional Pain Syndrome I (Reflex Sympathetic Dystrophy)*, 96 ANESTHESIOLOGY 1254-60 (2002) (filed as Ex. 11a).

In addition to the above, Dr. Kinsbourne cited three case reports in support of his theory.<sup>18,19,20</sup> While case reports are not robust evidence, they do constitute some evidence with which petitioners can meet their burden in the Vaccine Program. *See Contreras v. Sec’y of Health & Hum. Servs.*, 107 Fed. C. 280 (Fed. Cl. 2012); *see also Capizzano* 440 F.3d at 1325-26.

Kwun et al. reported the case of a 17-year-old girl who received the H1N1 vaccine. Approximately seven hours later, she reported tingling, as well as pain and edema from the arm to the fingers. Kwun at 1. She also developed weakness of her left upper arm such that she was not able to lift her arm over her shoulder. *Id.* Her doctor diagnosed her with CRPS. *Id.* Kwun concluded that “injection trauma and stress or psychological factors were associated with the onset and maintenance of symptoms of CRPS.” *Id.* at 3.

Richards et al. discussed five cases of CRPS temporally associated with vaccination. The authors proposed that “intramuscular immunisation is sufficient painful stimulus to trigger the development of CRPS-1, and that it is the process of a needle penetrating the skin that is the trigger, rather than a particular vaccine antigen or adjuvant being causally related.” Richards at 3. The article concluded by noting, “this case series of CRPS type 1 in adolescents temporally associated with immunisation reflect a known complex pain response to a painful stimulus.” *Id.*

Jastaniah et al. examined three instances of CRPS following Hepatitis B vaccination. The authors noted that “it seems likely that HBVx (either the trauma or the component of a vaccine) precipitated the clinical syndrome in this predisposed group.” Jastaniah at 804. The authors further indicated that they could not attribute causation of CRPS to the Hepatitis B vaccinations “given the low reported case rate and the absence of long-term follow-up.” *Id.*

Dr. Callaghan disagrees that a needle stick can cause CRPS. In support of this position, he cited to a retrospective epidemiological analysis of 1,043 CRPS patients. *See Ott & Maihöfner*. Dr. Callaghan described the findings of this article: “the largest case series investigating antecedent events in 1,043 patients with CRPS found that fractures (42%), blunt traumatic injuries (21%) and surgery (12%) were the most common causes.” Third Callaghan Rep. at 1. Dr. Callaghan further

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<sup>18</sup> Kwun et al. *Complex regional pain syndrome by vaccination: A case of complex regional pain syndrome after vaccination of influenza A(H1N1)*, PEDIATR INT 2012; 54: e4-e6 (filed as Ex. 11b) (hereinafter “Kwun”).

<sup>19</sup> Richards et al., *Complex regional pain syndrome following immunisation*, 97 ARCH DIS CHILD; 913-15 (2012) (filed as Ex. 11d) (hereinafter “Richards”).

<sup>20</sup> Jastaniah et al., *Complex Regional Pain Syndrome After Hepatitis B Vaccine*, 143 J PEDIATR, 802-04 (2003) (filed as Ex. 11e) (hereinafter “Jastaniah”).

stated that “[o]nly a single case of vaccination prior to CRPS was reported (0.09%), which is far below what would be expected based on chance alone.” *Id.*

Epidemiologic evidence is relevant with respect to *Althen* prong one. *See, e.g., D’Tiole v. Sec’y of Health & Hum. Servs.*, 2016 U.S. Claims LEXIS 2003 (Fed. Cl. Spec. Mstr. Nov. 28, 2016), *aff’d*, 132 Fed. Cl. 421 (2017); *Blackburn v. Sec’y of Health & Hum. Servs.*, No. 10–410V, 2015 WL 425935, at \*28–30 (Fed. Cl. Spec. Mstr. Jan. 9, 2015). However, this type of evidence is not required in order for a petitioner to establish that a vaccine can cause an injury. A vaccine injury is a rare event that cannot be disproved because a vaccinee did not experience a response consistent with that of the general population. *See Harris v. Sec’y of Health & Hum. Servs.*, No. 10–322V, 2014 WL 3159377, at \*11 (Fed. Cl. Spec. Mstr. June 10, 2014) (finding that epidemiologic studies cannot absolutely refute causal connections, because it is possible that a larger study could always detect an increased risk), *mot. for review dismissed*, 2015 U.S. App. LEXIS 7921 (Fed. Cir. 2015).

It is settled that “close calls” as to the causal link between a vaccine and the injury asserted by a Petitioner should be resolved in favor of the petitioner. *Knudsen by Knudsen*, 35 F.3d at 549. Although the precise biological mechanism as to how needle stick can cause CRPS is not yet known, the medical literature and case reports filed in this case, along with the opinion of Dr. Kinsbourne provide preponderant evidence with respect to the first *Althen* prong.

## 2. Althen Prong 3

The timing prong contains two parts. First, a petitioner must establish the “timeframe for which it is medically acceptable to infer causation” and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff’d without op.*, 503 F. App’x 952 (Fed. Cir. 2013).

In this case, Petitioner developed pain in her left upper arm 15 minutes after her flu vaccine. Ex. 4 at 44. Dr. Kinsbourne opined that this initial arm pain constituted the beginning of her CRPS. *See Third Kinsbourne Rep.* at 1. I find that this opinion is supported by the evidence in the case.

Dr. Kinsbourne has further opined that 15 minutes is an appropriate temporal interval between vaccination and onset of CRPS. *See First Kinsbourne Rep.* at 5. He based that opinion primarily on the Maleki article. Maleki et al., *Patterns of spread in complex regional pain syndrome, type I (reflex sympathetic dystrophy)*, 88 PAIN 259-66 (2000) (filed as Ex. 16e) (hereinafter “Maleki”). In that article, the authors analyzed the spread of disease in 27 patients who were previously diagnosed with CRPS. This study documented the interval between the initial trauma and onset of CRPS. In nine of the 27 patients (33%), onset is documented to have occurred immediately after the initial trauma/injury. Maleki at 262.

Dr. Kinsbourne also pointed to case reports of CRPS, where the authors describe onset of symptoms as immediate. *See e.g.,* Richards (describing immediate onset of numbness or severe pain after vaccination in two of five CRPS subjects, and onset within one hour to “hours” in two others); Kwun (describing one CRPS patient who developed pain, edema, and color change seven

hours after vaccination); Jastaniah (detailing four cases of CRPS which began between 15 minutes and one hour after vaccination).

Because the precise cause of CRPS is unknown, it is difficult to articulate the rationale behind an appropriate temporal interval between vaccination and injury. In citing to the Maleki article as well as the above-mentioned case reports, Dr. Kinsbourne has highlighted that there is circumstantial evidence that onset of CRPS can occur immediately after vaccination. I find this evidence is sufficient to meet Petitioner's burden with respect to the third *Althen* prong. *See Althen* ("the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.") 418 F.3d at 1280.

### 3. *Althen* Prong 2

Under *Althen*'s second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano*, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions<sup>21</sup> may be sufficient to satisfy the second *Althen* prong.

#### a. *The Onset of Petitioner's Arm Pain 15 Minutes after Vaccination Helps Establish that the Vaccine Was a but-for Cause of her Condition*

Petitioner's upper left arm pain began 15 minutes after she received her flu vaccine in her left shoulder. This fact was well-documented in her contemporaneous medical records. *See* Ex. 4 at 24, 29, 32, 43, 44. Prior to the administration of the vaccine, Petitioner was not experiencing

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<sup>21</sup> Several of Petitioner's treating physicians have articulated a link between her flu vaccination and her development of arm pain. Petitioner visited Dr. Fuller, her primary care doctor on September 29, 2015, 11 days after her flu vaccine. Dr. Fuller assessed her with "Myalgias following a flu vaccine. Possibly related to the flu vaccine." Ex. 4 at 44. On September 30, 2015, Petitioner was seen by Dr. Shih at UMass Memorial Hospital. Dr. Shih noted that Petitioner presented with bilateral myalgia that began after her flu vaccination. In the assessment portion of the record, Dr. Shih noted that Petitioner's bilateral arm pain "may be related in some way to the flu shot." Ex. 4 at 43. Petitioner visited Dr. Eisenstock on December 11, 2015. Dr. Eisenstock noted that Petitioner's symptoms "appear to be temporarily correlated with flu vaccine." Ex. 4 at 30. Further, in a letter dated September 21, 2018, Dr. Eisenstock wrote, "Given a correlation in time with receiving the flu shot, I would entertain the possibility of a related complex regional pain syndrome...." Ex. 12.

Dr. Fuller, Dr. Shih, and Dr. Eisenstock each noted in the medical records that the onset of Petitioner's pain began after her vaccination. Each also expressed their belief that Petitioner's symptoms of arm pain may have been caused by her vaccination. While this evidence would certainly be stronger if the treating physicians had offered a conclusive opinion, it is nonetheless some evidence that I have considered in reaching my determination in this case.

any pain. She was evaluated by Dr. Fuller on September 11, 2015 (seven days before her vaccination). The medical record from this visit noted that Petitioner had “[g]ood range of motion of shoulders, elbows, wrists with no active synovitis.” *Id.* at 45. While it is an often-cited tenet in the Vaccine Program that a close temporal interval between a vaccination and an injury does not prove causation, I find it would be inappropriate to ignore what appears to be the obvious cause of Petitioner’s left arm pain, pain which under Petitioner’s theory marked the beginning of her CRPS. As Dr. Kinsbourne stated in his report, “for pain of cervical origin so suddenly to arise at the time of vaccination by coincidence strains credulity.” First Kinsbourne Rep. at 3. I agree with this assessment based on the specific facts of this case.

The fact that Petitioner has established that vaccination can cause CRPS and that the timing prong has been met helps establish that she has also demonstrated that vaccination was a but-for cause of her condition. The Federal Circuit has provided guidance with respect to this issue.

Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the “but-for” prong of the causation analysis. *See Capizzano*, 440 F.3d at 1326 (finding medical opinions that explain how a vaccine can cause the injury alleged coupled with evidence demonstrating a close temporal relationship “are quite probative” in proving actual causation).

*Pafford*, 451 F.3d at 1358. *See also Contreras* (finding that there is a “logical overlap between the three *Althen* prongs, and that evidence that goes to one prong may also be probative for another prong”). 107 Fed. Cl. at 295. I find that Petitioner has presented preponderant evidence in support of the second *Althen* prong.

## VII. Conclusion

Based on the foregoing, I conclude that Petitioner has met her burden of proof under *Althen*. Accordingly, Petitioner is entitled to compensation. An order regarding damages will issue shortly.

**IT IS SO ORDERED.**

**s/ Katherine E. Oler**  
Katherine E. Oler  
Special Master